

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS***Summary of Amendments Made***

Claims 1-12 are still pending. Claims 1-12 have been amended to provide consistency within the claim language (also claim 9 did not end with a period). Note also that the "optional" nature of the cationic polymer in claim 1 has been deleted. It is believed that no new matter has been added.

Election/Restriction Requirement

The applicants petitioned the finality of the restriction requirement under 37 CFR 1.144 on 26 November 2002. The petition was granted on 12 February 2003 and as such the examiner's restriction/election of species requirement is withdrawn.

35 U.S.C. 112, second paragraph rejection

Claims 1, 4-8, 10 and 11 were rejected by the examiner for the reasons indicated in paragraphs (i)-(vi) on pages 4 and 5 of the examiner's office action. At the outset, the applicants submit that several of the rejections appear to cast aspersions on previously issued U.S. patents (see MPEP 1701 - Office Personnel Not to Express Opinion on Validity or Patentability of Patent). Applicants response below correspond to the paragraph numbers used by the examiner:

- (i) "Lipids and lipophilic constituents" rejection - These terms are well defined in the art and one of ordinary skill would be apprised of the scope of the limitation (previously used in claims of at least two other U.S. patents at the time of this response). The remaining questions under this paragraph have been addressed by the amendments to the claims.
- (ii) "parenthetical" rejection - While it is believed that one of ordinary skill in the art would be able to ascertain that the parenthetical expression refers to a mixture of the recited ingredients, in order to expedite prosecution, the claims have been amended to refer to the expression in terms of text. It is believed that no new matter has been added nor has the scope of the original expression been narrowed.
- (iii) The percent by weight descriptions have been added to the claims in the above amendments.
- (iv) "derivatives" rejection - Claims cannot be read in a vacuum and in this regard the term "derivatives" is used as part of the phrase "cationic cellulose derivatives". It is unclear why one of ordinary skill would not be apprised of the scope of such a phrase. The examiner is reminded that MPEP 2173.04 states that "Breadth of a claim is not to be equated with indefiniteness" (see also

in re Miller, 441 F.2d 689, 169 USPQ 597 (CCPA 1971)). Moreover, the terms have well known meanings in the art, e.g. the term "cellulose derivative" appears in the claims of 957 U.S. patents as of the date of this response.

- (v) "condensation products of polyglycols and amines" rejection – The examiner is reminded that MPEP 2111.01 states that the words of a claim must be given their "plain meaning" unless they are defined in the specification (see also *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)). Each of the terms in the phrase have a definitive meaning within the art and as such one of ordinary skill in the art would be able to contemplate the scope of compounds defined by the term. By way of example, the following definitions are from the McGraw-Hill Dictionary of Chemical Terms:

- (a) condensation reaction: One of a class of chemical reactions involving a combination between molecules or between parts of the same molecule.
- (b) polyglycols: A dihydroxy ether derived from the dehydration (removal of a water molecule) of two or more glycol molecules; an example is diethylene glycol, $\text{CH}_2\text{OHCH}_2\text{OCH}_2\text{CH}_2\text{OH}$.
- (c) amines: One of a class of organic compounds which can be considered to be derived from ammonia by replacement of one or more hydrogens by organic radicals.

- (vi) "cationic biopolymers" rejection - As stated above in (iv), breadth does not equal indefiniteness. In this case the burden is even greater as the claim is directed to a specific type of biopolymer, i.e. a cationic one. Moreover, the terms have well known meanings in the art, e.g. the term "biopolymers" appears in the claims of 203 U.S. patents as of the date of this response.

35 U.S.C. 103(a) rejections

- (1) Claims 1, 3, 4, 7 and 8 were rejected by the examiner as being obvious over Fänger et al. (U.S. Patent 6,153,204).
- (2) Claims 1, 2, 9 and 10 were rejected by the examiner as being obvious over Fänger et al., *ibid.* in view of Mahieu et al. (U.S. Patent 5,616,746) and Phillippe et al. (U.S. Publication 2002-0064539 A1).
- (3) Claims 1, 5, 6, 11 and 12 were rejected by the examiner as being obvious over Fänger et al., *ibid.* in view of Albacarys et al. (U.S. Patent 6,338,855).

It is presumed that rejection (1) was made due to the optional nature of element (d) of claim 1. As this has been deleted from the claim language, attention is directed toward rejections (2) and (3).

Fanger was acknowledged by the examiner to have at least two differences over the applicants' claims:

- (i) "The reference lacks the water phase comprising greater than 80% of the emulsion."; and
- (ii) "The reference lacks cationic polymers."

(A) Inherency of viscosity limitations not shown

Moreover, it was presumed that the Fanger reference taught similar viscosity as the applicants' claimed invention (with or without the presence of a cationic polymer) because several of the ingredients of Fanger's composition corresponded to the ingredients of the applicants claims.

However, when making the "as a whole" determination of the Fanger reference, it is clear that Fanger's compositions require the presence of a starch esterified with one or more n-octenylsuccinate radicals (see e.g. col. 4, lines 20-36, claim 1 and Abstract). If there is a reason why one of ordinary skill in the art would view such a composition containing this ingredient to inherently have the viscosity claimed in the applicants' invention, it has not been established by the examiner.

Further still, the examiner appears to use Fanger on the premise that the applicants claims could encompass the starch esterified with one or more n-octenylsuccinate radicals because of the applicants use of "comprising" language. As such, the burden on the examiner for showing inherency for viscosity is not limited to the Fanger reference but towards a water-in-oil emulsion with the stated limitations of the applicants claim 1 **and including** a starch esterified with one or more n-octenylsuccinate radicals.

MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof) states "*The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), see also *Mentor H/S, Inc. v. Medical Device Alliance, Inc. (Mentor II)*, 244 F.3d 1365, 58 USPQ2d 1321 (Fed. Cir. 2001) and *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

(B) No motivation or expectation of success to combine cationic polymers to invention of Fanger

In order to address the lack of a teaching for a cationic polymer in Fanger, the Albacarys reference is relied upon for their general teachings to cationic polymers (col. 26 through 42 were referred - this is part of a virtual infinite amount of "additional ingredients" which could be added to the article of Albacarys which actually begins on col. 15), i.e. rejection (3).

However, these general teachings apply to making additions to Albacarys' cleansing articles comprising a water insoluble substrate. There is no teaching or suggestion that these general teachings are equally applicable to the water-in-oil emulsions taught by Fanger. MPEP 2143 states that "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)"

If the examiner argues that she is only using a specific portion of the Albacarys reference to be combined with the Fanger reference, it has previously been held that "It is impermissible within the

framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." (see *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965)). More recently, it has been held that "...*Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.*" see *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998).

Even if adequate motivation was provided or was available to combine the references, this still does not address the viscosity limitation of the applicants' claims, i.e. there is no reasonable expectation of success that adding a cationic polymer to the invention of Fanger would result in an emulsion with the applicants' claimed viscosity limitations.

(C) Water Phase Limitation Is Another Variable That Requires Further Reconstruction to Arrive at Applicants Claimed Invention

Pertaining to rejection (2), the Mahieu et al. and Phillipe et al. references are used to address the water content limitation of the dependent claims (most particularly, claims 2 (greater than 80% by weight) and 9 (greater than 85% by weight). The response of (A) and (B) would also apply here. Further, the Mahieu et al. and Phillipe et al. references do not teach or suggest modification of Fanger or the invention represented by Fanger in view of Albacarys.

The ultimate determination whether an invention would have been obvious under 35 U.S.C. § 103 is a legal conclusion based on underlying findings of fact (see *In re Kotzab*, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000)). However, the water content attributed by the examiner to Mahieu et al. and Phillipe et al. are for their own respective inventions and there is no factual basis for the assertion that these water limitations are equally applicable for the invention of Fanger et al.

Provisional Obviousness-Type Double Patenting Rejection

Claims 1-12 were provisionally rejected for obviousness-type double patenting over claims 6-12 (SN: 09/328,727); claims 1-5 (SN: 09/963,161) and claims 1-6 and 8 (SN: 09/428,421) by the examiner.

While the applicants do not necessarily agree with this provisional rejection, the applicants request that this rejection be held in abeyance as none of the recited applications have been allowed. If this application is the first allowed application, this will become a moot point as MPEP 822.01 recites that "If the 'provisional' double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the 'provisional' double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. See also MPEP § 804.01 and § 822."

Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (11 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 17 April 2003

By: Vilma I. Fernandez

COPY OF CLAIMS SHOWING AMENDMENTS MADE**1. Water-in-oil emulsions**

- (a) with a **water phase with a** content of water and optionally water-soluble substances totalling at least 75% by weight and **an oil phase** with a content of lipids, emulsifiers and lipophilic constituents totalling at most 25%, based in each case on the total weight of the **[preparations]** **emulsions**.
- (b) whose oil phase is chosen from the group of lipids or lipid mixtures, where the total polarity of the **[lipid]** **oil** phase is between 20 and 30 mN/m,
- (c) comprising at least one interface-active substance, selected from the group consisting of alkylmethicone copolyols, alkylidimethicone copolyols, and mixtures thereof,
- (d) **[optionally,]** comprising one or more cationic polymers,

and having a viscosity at 25°C which is less than 5000 mPa·s.

- 2. **The water-in-oil emulsions of** **[Emulsions according to]** Claim 1, wherein the amount of water and water-soluble substances is greater than 80% by weight, based on the total weight of the emulsions.
- 3. **The water-in-oil emulsions of** **[Emulsions according to]** Claim 1, wherein the interface-active substances are selected from the group consisting of cetyltrimethicone copolyol, lauryltrimethicone copolyol and mixtures thereof.
- 4. **The water-in-oil emulsions of** **[Emulsions according to]** Claim 1, wherein the oil phase consists of at least 50% by weight, of at least one substance selected from the group consisting of **[(butyldecanol + hexyldecanol + hexyloctanol +**

butyloctanol)), hexyldecanol, octyldodecanol, dicaprylyl ether, caprylic/capric triglycerides, octyl palmitate, isopropyl stearate, octyl octanoate, C₁₂₋₁₅-alkyl benzoates, cetylstearyl isonanoate, butylene glycol caprylate/caproate, tricaprylin, octyldodecyl myristate, di-C₁₂₋₁₃-alkyl tartrates, caprylic/capric diglycerol succinate, octyl isostearate, stearyl heptanoate, cocoyl caprylate/caproate, isopropyl palmitate, cetylstearyl octanoate, [and] octyl stearate and a mixture of butyldecanol/hexyldecanol/hexyloctanol/butyloctanol.

5. The water-in-oil emulsions of [Emulsions according to] Claim 1, wherein cationic polymers are present in an amount of from 0.01 to 10% by weight, based on the total weight of the emulsions.
6. The water-in-oil emulsions of [Emulsions according to] Claim 1, wherein said cationic polymer(s) is/are selected from the group consisting of cationic cellulose derivatives, cationic starch, copolymers of diallylammonium salts and acrylamides, quaternized vinylpyrrolidone/vinylimidazole polymers, condensation products of polyglycols and amines, quaternized collagen polypeptides, quaternized wheat polypeptides, polyethyleneimine, cationic silicone polymers, copolymers of adipic acid with dimethylaminohydroxypropyldiethylenetriamine, copolymers of acrylic acid with dimethyldiallylammonium chloride, polyaminopolyamides, cationic chitin derivatives, cationic guar gum, quaternized ammonium salt polymers, and cationic biopolymers.
7. The water-in-oil emulsions of claim 1, wherein said contents of lipids, emulsifiers and lipophilic constituents total at most 20% by weight, based on the total weight of the emulsions.
8. The water-in-oil emulsions of claim 5, wherein the content of water and water-soluble constituents is between 75 and 80% [,]by weight, based on the total weight of the emulsions.

9. The water-in-oil emulsions [emulsion] of claim 2, wherein the amount of water and water-soluble substances is greater than 85% by weight, based on the total weight of the emulsions.
10. The water-in-oil emulsions of claim 4, wherein the oil phase consists of at least 75% by weight of said at least one substance, based on the total weight of the emulsions.
11. The water-in-oil emulsions of claim 5, wherein said cationic polymers are present in an amount of from 0.25-1.25% by weight, based on the total weight of the emulsions.
12. The water-in-oil emulsions of claim 6, wherein said cationic biopolymers are selected from the group consisting of chitosan, having an average molecular weight of from 50,000 to 2,000,000 g/mol, determined by means of gel permeation chromatography, and a degree of acetylation of from 10 to 99%, determined by means of ¹H-NMR.